SUMMARY and CONCLUSIONS

University of the Pacific School of Dentistry Clinical Research Protocol WHLS - 005

Effect of Frequent Daily Use of Microdent® (a melt-emulsion of polydimethylsiloxane in Poloxamer 407) containing, Sorbitol-based, Sugar-free Mints in Reducing Dental Plaque Accumulation Between Brushings: A Double Blind, Cross-Over Treatment Design

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PURPOSE:

The purpose of this clinical trial is to compare in normal human subjects the effect on dental plaque accumulation, between brushings, of multiple daily uses of a sorbitol-based, sugar-free mint containing 1.5% of a melt-emulsion of polydimethyl siloxane (PDMS) in Poloxamer 407 (a food grade surfactant) which acts as an agent to both clean and modify the surface free energy of the teeth versus a placebo mint without the melt-emulsion ingredient. It is an additional purpose to compare three different melt-emulsion compositions where the PDMS is of differing molecular weights and concentration in the Poloxamer surfactant.

PROTOCOL:

Subjects were instructed to refrain from brushing or eating for 12 hours prior to examination. Subjects were scheduled for the same time for each evaluation to further eliminate variation. The plaque was stained just before the baseline examination for each cell and subjects received a rubber cup prophylaxis to reduce plaque to zero at the beginning of each product-use period. At each 48 hr Final evaluation period (Final) the plaque was stained just before examination.

Examinations were scored utilizing and expanded Turesky Modification of the Quigley-Hein Method (Shaver-Schiff). Subjects were instructed to refrain from brushing, flossing or mouth rinses as well as the use of chewing gums or mints except for those provided in the study.

For each cell, subjects were given two coded packets containing 6 mints (Test or Placebo) and instructed to dissolve one mint without chewing after each meal, once between meals and at bedtime for both days of the test period. A 5-day washout period with normal oral hygiene separated each of the product-use cells.

A series of crossover cells where the same subjects utilized all products was selected to reduce subject-to-subject variation due to individual propensity to accumulate plaque. Cell size to completion varied from 12 to 9 to 7, as various subjects dropped out of the series in certain weeks. The results were sufficiently dramatic, and the baselines so consistent from week to week that, even with the small cell size, significant differences of $p < 0.0001$ were observed between placebo and test mints.

ADVERSE EFFECTS:

No adverse effects of tooth surfaces or soft tissue were noted following and of the Placebo or Test Mint product-use periods.

CONCLUSIONS:

Each of the three Test Mints containing a melt-emulsion ingredient very significantly (typically $p<0.0001$) reduced the accumulation of plaque when compared to either the baseline or the Placebo Mint.
There was a slight increase (8.5%)in plaque accumulation over the 48 hour product-use period for the Placebo Mint, as would be expected. There were no significant differences between any of the baseline evaluations. There were no significant differences between Test Mints at the 48-hour evaluation periods.

> *The three Test Mints containing the melt-emulsion ingredient demonstrated an average reduction of 32.3% in plaque accumulation between brushings, compared to the Placebo Mint when used six times per day across a 48 hour, between-brushings period.*

Similar differences in PI means were seen when the tooth surfaces were segregated into Proximal, Smooth and Posterior surfaces. Of particular note is that the active ingredient in the Test Mints induced excellent plaque reduction on those surfaces where normal brushing habits are typically less effective, i.e., the interproximal and posterior surfaces.

DATA AND STATISTICAL SUMMARY:

Table I on the following page summarizes the whole mouth mean Plaque Index (PI) scores of the products, the change in PI from baseline or compared to the Placebo Final score, the percent change in PI across the between brushings test period, and the statistical significance of each difference in means.

The mouth-by-mouth raw data, tables of statistical analysis for each Group and comparisons between Groups are included in the Raw Data section.

TABLE I

SUMMARY OF WHOLE MOUTH MEANS of PLAQUE INDEX (PI) EVALUATIONS BY TEST PRODUCT
with
CALCULATION OF PI DIFFERENCES and PERCENT REDUCTION IN PLAQUE ACCUMULATION
and
STATISTICAL SIGNIFICANCE

PRODUCT	CODE	PI BASE	PI FINAL	Δ PI FINAL v. BASE	% Δ PI Final v. Base	Stat. Sig. v. Base	Δ PI FINAL v. PLACEBO	% Δ PI FINAL v. PLACEBO	Stat. Sig. v. Placebo
PLACEBO	111	2.12	2.30	+ 0.18	+ 8.5	p<0.05	---	---	---
Test Mint A 600,000cs PDMS @ 10% (1.5% emulsion in Mint)	222	2.01	1.61	- 0.40	- 19.9	p<0.005	- 0.69	- 30.0	p<0.0001
Test Mint B 2,500,000cs PDMS @ 10% (1.5% emulsion in Mint)	555	2.08	1.57	- 0.51	- 24.5	p<0.0005	- 0.73	- 31.7	p<0.0001
Test Mint C 2,500,000cs PDMS @ 10% (1.5% emulsion in Mint)	666	2.14	1.49	- 0.65	- 30.4	p<0.0001	- 0.81	- 35.2	p<0.0001